
4.0 510(k) SUMMARY

510(k) Notification K 123696

GENERAL INFORMATION

Applicant:

EndoShape, Inc.

Phone:

Contact Person:

Michael Parmenter

Quality Manager

EndoShape, Inc.

Phone: 303-951-6898 x106

Fax: 303-416-8849

OCT 25 2013

Date Prepared:

November 30, 2012

DEVICE INFORMATION

Trade Name:

Medusa™ Vascular Plug

Generic/Common Name:

Vascular Embolization Device

Classification:

21 CFR§870.3300, Class II

Product Code:

KRD

PREDICATE DEVICE(S)

- Cook Embolization Coils (Pre-Amendment)
- Amplatzer Vascular Plug (K031810)

INDICATIONS FOR USE

The Medusa™ Vascular Plug is intended for arterial and venous embolizations in the peripheral vasculature. The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and guide wires should be employed.

DEVICE DESCRIPTION

The Medusa™ Vascular Plug is a coil-based occlusion device intended for embolization procedures in the peripheral vasculature. The Medusa™ Vascular Plug consists of an implant and a delivery system. The implant is constructed of multiple polymer coils that are pre-loaded on to the delivery system. The Medusa™ Vascular Plug coils are delivered concurrently for vascular occlusion in a single application. Like predicate embolic coils, vascular occlusion with the Medusa™ Vascular Plug is achieved by mechanical flow restriction resulting from coil pack delivery that leads to thrombus formation and rapid cessation of blood flow.

SUBSTANTIAL EQUIVALENCE

The Medusa™ Vascular Plug and the predicate devices, the Cook Coils and the Amplatzer, have the same intended use and use similar technological characteristics to achieve the same mechanism of action. Any technological characteristics that are unique to the Medusa™ Vascular Plug have been validated to raise no new issues of safety or effectiveness. Therefore, the Medusa™ Vascular Plug is substantially equivalent to the Cook Coils and the Amplatzer.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Medusa™ Vascular Plug to support a determination of substantial equivalence to the predicate devices. The non-clinical, bench and animal testing included:

- Design verification and bench validation studies
- *In-vivo* animal validation study
- Biocompatibility
- Sterilization
- Packaging and shelf-life

The collective results of the non-clinical testing demonstrate that the Medusa™ Vascular Plug meets the established specifications necessary for consistent performance for its intended use.

ANIMAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

In-vivo animal testing was conducted to demonstrate that the Medusa™ Vascular Plug exhibits substantially equivalent occlusion performance in a clinically relevant model. A direct comparison was conducted in accordance with Good Laboratory Practices (GLP) in an ovine model to provide a direct comparison of the Medusa™ Vascular Plug and the Cook

Coils. Animals were sacrificed at 33 and 95 days post-implantation. At these time points, test subjects underwent angiographic assessment of stability and durability of occlusion (occlusion assessed by the physician), followed by euthanasia, gross necropsy, microscopic examination, and histopathology.

The Medusa™ Vascular Plug exhibited performance equivalent to the predicate Cook stainless steel embolization coils through the 95-day time point, resulting in comparable stability of occlusion, comparable occlusion times, and comparable or better durability of occlusion. At the same time, the Medusa™ Vascular Plug did not exhibit any acute or chronic complications, or raise any other questions of safety, demonstrating that it is as safe as the predicate coils. The Medusa™ Vascular Plug was shown to be substantially equivalent to the predicate coils in this chronic study and the results support a substantially equivalent determination.

CONCLUSION

The results of the nonclinical testing demonstrate that the new technological characteristics employed by the Medusa™ Vascular Plug do not raise any new issues of safety or effectiveness. Therefore, the Medusa™ Vascular Plug is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

Endoshape, Inc.
c/o Mr. Michael Parmenter
Quality Manager
2450 Central Avenue #1
Boulder, CO 80301

Re: K123696

Trade/Device Name: Medusa™ Vascular Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 9, 2013
Received: October 10, 2013

Dear Mr. Parmenter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

ENDOSHAPe, INC.

MEDUSA™ VASCULAR PLUG
510(k) PREMARKET NOTIFICATION

3.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Medusa™ Vascular Plug

Indications For Use:

The Medusa™ Vascular Plug is intended for arterial and venous embolizations in the peripheral vasculature. The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and guide wires should be employed.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lisa M. Lim -S 2013.10.24
15:55:44 -04'00'